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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,066	05/06/2005	Jong-Soo Woo	Q87744	2761

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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,066

Applicant(s)

WOO ET AL.

Examiner

Lezah W. Roberts

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12 Feb 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed February 12, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to the Election of Species

Applicant's election without traverse of Ibuprofen in the reply filed on February 12, 2007 is acknowledged.

Claims

Claim Rejections - 35 USC § 103 - Obviousness

1) Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2002/0032171). The rejection is maintained.

Applicant argues although Chen et al. disclose using ethanol as a solubilizer or solvent for the pharmaceutical composition disclosed therein, it is silent in regards to stability toward pH change, formation of microparticles and improved bioavailability (see remarks, page 4). Applicant also points to the Declaration filed under 37 CFR 1.132 by the Inventor. The Declaration discloses an example using Applicant's method of the instant claims and samples with varying amounts of ibuprofen where the ingredients have been mixed together simultaneously. The instant invention is not taught, suggested or implied by the cited reference. This argument is not persuasive.

In regards to the properties of the compositions made by the instant method, the claims do not recite properties they recite a method of making a microemulsion concentrate for oral administration. The Declaration discloses a comparative study but does not disclose what is in the examples and relies on the instant specification for Example 1. The samples a, b, c and d are only defined by the amount of ibuprofen that is in the samples. In regards to the components being mixed simultaneously, Applicant does not disclose how this is done. There would have to be some type of order of mixing the components even if the components were mixed one after the other. It is not likely that all the components are poured into to a vessel at exactly the same time. Applicant does not appear to clearly disclose how the methods of making the compositions vary from sample to sample. Furthermore Chen et al. discloses the ethanol as a solubilizer for the drug, therefore it would be obvious to one of ordinary skill in the art to dissolve the drug in the solubilizer before adding other components to ensure the drug was fully dissolved. The reference also discloses the therapeutic agent is solubilized in either the triglyceride, the surfactant or both, meaning the therapeutic agent may be dissolved first followed by the addition of the other components. As stated in the prior Office Action, selection of any order of mixing ingredients is *prima facie* obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930).

2) Claims 1-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,458,373). The rejection is maintained.

See Applicant's arguments above. Applicant further argues in regards to Lambert et al. that the preparation of the pharmaceutical composition of example 4 was made by concurrent mixing of the active ingredient, tocopherol, the surfactant, TPGS and ethanol followed by the removal of ethanol. This would lead to precipitation of the active ingredient and low emulsion stability. This argument is not persuasive.

See arguments above. Example 4 is just one example disclosed in the reference. The reference also discloses "the pharmaceutical compositions of the invention are typically formed by dissolving a therapeutic agent in ethanol to form a therapeutic agent solution". The ethanol is removed at the end to make a substantially free ethanol composition (see col. 4, lines 6-18). This encompasses Applicant's instant claims.

Claims 1-11 are rejected.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in cursive script, appearing to read "Leah Roberts", with a large, stylized loop at the end.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in cursive script, appearing to read "Frederick Krass", with a long, horizontal flourish extending to the right.